No. 89-243

IN THE

Supreme Court of the United States

OCTOBER TERM, 1989

ELI LILLY AND COMPANY,
Petitioner,

v.

MEDTRONIC, INC.,
Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENT

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QUESTION PRESENTED

Whether a patent can be employed to foreclose experimental testing of medical devices to develop and submit information under the Federal Food, Drug and Cosmetic Act despite the existence of 35 U.S.C. § 271(e)(1) which declares it is not an act of patent infringement to "make, use or sell a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs."

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A. The Statutory Scheme

The Food and Drug Administration ("FDA") regulates various products including human and animal drugs, medical devices, food additives, and color additives. Federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. §§ 301-93 (1982 & Supp. I 1983 - Supp. V 1987). *as amended by* Pub. L. No. 100-670, 102 Stat. 3971 (1988); Public Health Service Act ("PHS Act"), 42 U.S.C. §§ 262-63 (1982 & Supp. V 1987). There are products in each of those categories that must be tested and approved before being sold to the general public. The testing necessary to secure FDA approval can be extensive and time-consuming.

The resulting regulatory delay in getting to market inherently conflicts with the goals and operation of the patent laws. The ability to exploit a patent monopoly may be minimal during those early years of a patent when the patentee is attempting to comply with regulatory prerequisites imposed by the FDA. Hence, the patentee's overall period of market exclusivity is effectively reduced from the seventeen years granted by the patent laws. Conversely, competitors seeking to enter the market with a competitive or improved invention after expiration of a patent are delayed by their own need to qualify their inventions under the FDA regulatory process. If that testing cannot be done until after the patent expires, the patentee enjoys an additional post-patent period of market exclusivity which Congress has called a "secondary patent."[1] Thus, FDA testing requirements

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1. H. Rep. No. 972, 100th Cong., 2d Sess., pt. 2, 15 (1988). It also has been dubbed a "regulatory patent":

> Once a manufacturer has gone through the [FDA pre-market approval] process, it gains what has been termed a "regulatory patent." That is, until other manufacturers of similar products go

can produce both a *de facto* reduction and a *de facto* extension of the patent term.

Congress dealt with those problems by enacting the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("DPC-PTR Act"). Two interrelated parts of Title II of the Act bear on the problems of *de facto* alteration of patent rights by FDA testing requirements. 35 U.S.C. §§ 156 & 271(e) (1982 & Supp. V 1987), *as amended by* Pub. L. No. 100-670, 102 Stat. 3971 (1988). The Act's provisions for extending the patent term counteract the *de facto* reduction by providing an express patent extension related to the amount of time necessary to secure FDA approval. § 156. Patent term extension explicitly is made available to drug products and to "[a]ny *medical device* . . . subject to regulation under the Federal Food, Drug and Cosmetic Act." § 156(f)(1) (emphasis added). The Act also contains a provision that counteracts the *de facto* extension by permitting an otherwise-infringing "patented invention" to be used to develop information reasonably related to obtaining FDA regulatory approval. § 271(e)(1).

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through the PMA process, the manufacturer with a PMA for its device is the only one authorized to sell it in the United States. In some cases, a regulatory patent can provide more protection against competition than a patent issued by the Patent Office. Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 Food Drug Cosm. L.J. 511, 520 (1988). A commentator also has used the term "non-patent patent." Bennett, *Patent Certification: Procedural Protection for the Pharmaceutical Innovator*, 40 Food Drug Cosm. L.J. 317, 317 (1985).

Lilly asserts that *de facto* patent extension can be avoided by moving FDA testing to a noninfringing venue abroad. Pet. Br. 31 n.21. Aside from the fact that such foreign testing would work a discrimination against smaller domestic device makers, the FDA may not approve an exclusively foreign clinical trial. *See*, Respondent's Brief in Opposition to Petitioner's Reapplication for an Order to Recall and Stay the Mandate, at p. 4 & App. E.

It is the last provision that must be construed in this case. The question before the Court is whether section 271(e)(1) exempts otherwise-infringing activities involving a medical device being tested for the purpose of submitting information to the FDA under the FD&C Act or whether the section is limited to drugs. Resolution of that question depends principally on the text of Section 271(e)(1) as enacted in 1984 and in effect at the time of trial, which provided:

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913)) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.

At that time, the simultaneously enacted section 156 provided patent term extension for all products subject to FDA regulatory delay other than the animal products excluded by the parenthetical in section 271(e)(1).

Assistance in understanding the statutory scheme is also provided by considering the Generic Animal Drug and Patent Term Restoration Act of 1988, Pub. L. No. 100-670, 102 Stat. 3971 (1988), ("1988 Amendments"), which amended the FD&C Act and 35 U.S.C. §§ 156 and 271(e)(1). The 1988 Amendments changed section 156 by explicitly making new animal drugs and veterinary biological products (other than those made by genetic engineering techniques) eligible for patent term extension. Simultaneously, section 271(e)(1) was amended to extend the testing exemption to those same animal products (new material italicized):

> It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) *which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques)* solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs *or veterinary biological products.*

B. The Facts of this Case

In 1983 the predecessor-in-interest of petitioner Eli Lilly and Company ("Lilly") brought a patent infringement action against Medtronic to enjoin the testing to develop information on an implantable cardiac defibrillator for submission to the FDA.[2] Thirty-one devices involved in various stages of such testing were accused by Lilly as infringements.[3]

2. The patents allegedly infringed were U.S. Patent No. Re. 27,757 and No. 3,942,536. The '757 patent was to expire on October 26, 1988, but Lilly obtained a two-year extension of the patent under Section 156.

The notice required by Sup. Ct. R. 29.1 is provided in Respondent's Brief in Opposition to Petition for Writ of Certiorari at 1 n.1.

3. Two different Medtronic models were alleged to infringe by virtue of activities ranging from in-house laboratory tests, to in-house animal implants, to clinical implants in patients. Medtronic's Model 7215 Implantable Pacemaker Cardioverter Defibrillator ("PCD") is capable of automatically treating episodes of overly rapid heartbeat ("tachyarrhythmias"). The Model 7215 contains a microprocessor-controlled heart stimulator to deliver sequences of small pacemaker pulses or moderately sized "cardioverter" pulses to induce a return to normal heart rhythm without pain. If the arrhythmia degrades into a potentially fatal ventricular fibrillation, the device can deliver a high energy shock to terminate fibrillation. J. App. 66-67. Another Medtronic device alleged to infringe was the Model 7210. Both models were found at trial to infringe the '757 patent, but only the 7210 was found to infringe the '536 patent.

During pretrial proceedings, Medtronic moved to resolve the legal question whether 35 U.S.C. § 271(e)(1) shielded Medtronic from liability for infringement since Medtronic's devices were experimental, and the accused FDA testing activities had been undertaken to satisfy FDA compliance standards. The district court ruled that the section 271(e)(1) defense was "inapplicable to medical devices" and excluded any evidence at trial concerning Medtronic's defense under that statute. Pet. App. 19a. Hence, the record does not contain the evidence that would show that Medtronic's manufacture, use, and sale of the alleged infringing devices were "solely for uses reasonably related to the development and submission of information under" the FD&C Act within the meaning of section 271(e)(1). That issue has not been addressed or determined in this case.

The district court found the patents valid and infringed and entered an injunction against further infringement. Medtronic's appeal of that interlocutory injunction is the subject of this Court's review. The remainder of the case is not ripe for appeal since post trial motions on patent validity and infringement and other issues remain undecided by the district court. Hence, the basic issues of patent validity and infringement never have been reviewed, and Medtronic does not concede them here.

On appeal, the Federal Circuit reversed and held that section 271(e)(1) applies to medical devices.[4] Pet. App. 1a. After finding both the statutory language and legislative history "ambiguous," the court of appeals concluded that Congress' purpose in enacting section

4. The court of appeals did not consider Medtronic's other bases for vacating the injunction. Hence, if this Court reverses, the case should be remanded for consideration of those other bases. Lilly's request that this injunction be reinstated forthwith is inappropriate.

271(e)(1) was best achieved by reading the statute to include medical devices. The Federal Circuit observed that section 271(e)(1) was contained in the same legislation, the DPC-PTR Act, that provided for patent extensions in 35 U.S.C. § 156, and that "the benefits of patent extension are not restricted to drugs, but extend to medical devices." *Id.* at 5a. The court found "[n]o persuasive reason . . . why Congress would create an exception with respect to [FDA-driven experimental] activities for drugs only, particularly as medical devices receive the benefit of the companion patent term restoration legislation." *Id.* at 7a. Returning to the statutory language, the court held "that section 271(e)(1) allows a party to make, use, or sell *any type* of 'patented invention' if 'solely' for the restricted uses stated therein." *Id.*

Medtronic's latest version of a PCD, the Model 7216A which was developed after trial and is manufactured in Europe, is being clinically tested in the United States under an injunction modified after the court of appeals' ruling. Anticipating normal regulatory delays, the Model 7216A will not be approved by the FDA for general use until long after the '757 patent, as extended under 35 U.S.C. § 156, expires on October 26, 1990. J. App. 95, 99.

SUMMARY OF ARGUMENT

I. This case is governed by the plain language of 35 U.S.C. § 271(e)(1). Medtronic's PCDs were "patented invention[s]" and their testing was done under the FD&C Act which is "a Federal law which regulates . . . drugs." Both criteria of section 271(e)(1) are met.

"Patented invention" in section 271(e)(1) has an established broad and expansive meaning in the Patent

Act that encompasses all inventions including devices. The term cannot be restricted to human drug-related inventions by virtue of its own established meaning or the syntax in which it is used. Medtronic's PCD is irrefutably a "patented invention" as that term is used in section 271(e)(1).

Since Medtronic's PCDs were being tested under the FD&C Act, those activities were by definition "uses reasonably related to the development and submission of information under a Federal law which regulates . . . drugs." Congress used that phrase to refer to broad enactments including the FD&C Act and the Public Health Service Act ("PHS Act"). Even if "law which regulates . . . drugs" were construed (incorrectly) to refer to individual sections or subsections of the FD&C Act, rather than entire Acts, Medtronic still would prevail. The sections and subsections of the FD&C Act that regulate medical devices also regulate drugs. Therefore, regardless of the level at which the "law" specified in the section is approached, Medtronic's PCDs were tested under a "law which regulates . . . drugs."

II. This is also a case in which "only one of the permissible meanings" of section 271(e)(1)—Medtronic's—"produces a substantive effect that is compatible with the rest of the law." *United Savings Ass'n v. Timbers of Inwood Forest Assocs.*, 108 S. Ct. 626, 630 (1988). When Congress enacted the infringement exemption in section 271(e)(1), it simultaneously enacted patent term extension in section 156 which explicitly covers "medical devices." Section 271(e)(1) was intended to be coextensive. When granting patent term extension in section 156, Congress made clear that "[t]here should be no other direct or indirect method of extending patent term." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 46

(1984) [hereinafter H.R. Rep. 98-857(I)]. The parallel amendments made to sections 156 and 271(e)(1) during the original legislative process and afterward by statutory amendment show that the two sections have consistently moved in lockstep to provide an exemption for testing of the same inventions as are eligible for patent extension.

III. Other aids to statutory interpretation also support Medtronic's position. Congress' dominant policy goal in enacting section 271(e)(1) was to foster early competition in medical technology consistent with preservation of necessary patent incentives for innovation. That goal is advanced as much by exempting medical device testing as by exempting drug testing.

Lilly's focus on Congressional statements concerning the statute's effect on the drug industry does not evidence a Congressional intent contrary to the plain meaning of the statutory text. Were such an argument valid, it could be applied to prove incorrectly that section 156 does not apply to medical devices; the legislative history of section 156 is as devoid of mention of devices as is that of section 271(e)(1). There is no indication that devices were to be excluded from the exemption of section 271(e)(1). Many decisions of this Court have shown that statutes can have effects not mentioned in their legislative history.

Finally, it is implausible that Congress meant the hazy line between drugs and medical devices, which the FDA must draw for regulatory purposes under the FD&C Act, to have significance in the very different field of patent infringement.

IV. Even if this Court determines that section 271(e)(1) is limited to drugs, it should affirm the judgment of the Federal Circuit. Section 271(e)(1) aside,

FDA-mandated experimentation is not patent infringement. The purposes of the FD&C Act and the Patent Act, as well as the general constitutional mandate enforced by this Court in a long line of cases that patents last only for a limited and definite time, strongly counsels against holding FDA-mandated testing to be patent infringement.

ARGUMENT

Section 271(e)(1) exempts the manufacture, use, or sale of a patented invention "solely for uses reasonably related to the development and submission of information under a *Federal law which regulates . . . drugs.*"[5] (Emphasis added). Medtronic's devices were found to infringe Lilly's patents. Hence, by definition, Medtronic has been held to have made, used or sold a "patented invention." 35 U.S.C. § 271(a) (1982). The question presented for this Court to determine is whether the law under which Medtronic was testing the device, i.e., the FD&C Act, is a "Federal law which regulates . . . drugs."

Medtronic contends that the clause "which regulates . . . drugs" identifies the federal laws under which testing will be exempt, and not the kind of product on which testing may be done. Lilly asserts that section 271(e)(1) exempts testing of only the products mentioned at the end of the section, *i.e.*, drugs. All of Lilly's arguments stem from the same fact, that the section does not refer to medical devices by name. The implication of Lilly's position is that Congress purposely created an inequality between drug and medical device patents by making both extendable, but exempting FDA testing only in the case

5. The 1984 version is the version of Section 271(e)(1) referred to throughout the brief unless expressly stated otherwise.

of drugs. There is no indication that Congress intended any such inequality. The statute should be read—in accordance with its unambiguous terms—to cover medical devices tested under the FD&C Act.

I. THE PLAIN LANGUAGE OF SECTION 271(e)(1) CREATES AN EXEMPTION FROM INFRINGEMENT FOR FDA TESTING OF MEDICAL DEVICES

Direct application of the plain language of section 271(e)(1) is conclusive in this case. *United States v. Ron Pair Enters., Inc.*, 109 S. Ct. 1026, 1030 (1989) ("where, as here, the statute's language is plain, 'the sole function of the courts is to enforce it according to its terms.' "); *Southeastern Community College v. Davis*, 442 U.S. 397, 405 (1979).

A. "Patented Invention" In Section 271(e)(1) Has The Same Broad Meaning As In 35 U.S.C. § 101 And Is Not Modified By The Words "Federal Law Which Regulates . . . Drugs"

The first portion of section 271(e)(1) states that a "patented invention" may be exempted from infringement if used as specified under a "law which regulates . . . drugs." The phrase "patented invention," on its face, broadly applies to *any* invention used for purposes exempted by the section. Lilly, however, thrusts the word "drugs" to the forefront and argues that "Federal law which regulates . . . drugs" modifies and restricts "patented invention" so that "invention" really means drug-related invention. Pet. Br. 21.

The argument is unfounded. Lilly's contentions visit and revisit the word "drugs" in section 271(e)(1) without analysis of the text or the syntax of its use. The argument that "drugs" modifies and restricts "patented invention" (Pet. Br. 21) cannot survive careful scrutiny of how the word is used in the statute. It is an accepted principle of statutory construction that qualifying words refer only to the last antecedent.[6] The ordinary rules of grammar and syntax must be applied to the task of statutory interpretation. *Ron Pair*, 109 S. Ct. at 1030-31.[7]

The established usage of "patented invention" throughout Title 35 and in section 271 also makes Lilly's argument untenable. The term "patented invention" is defined by "broad general language" in the patent statute to include any new and useful "process, machine, manufacture, or composition of matter." 35 U.S.C. § 101 (1982). *Diamond v. Chakrabarty*, 447 U.S. 303, 315-16 (1980).

Patent infringement in turn is defined in section 271(a) using that broad term: "whoever without authority makes, uses, or sells any patented invention, within the United States during the patent term therefor, infringes the patent." Section 271(e)(1) provides that certain manufacture, use, or sale of a "patented invention" is not in-

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6. Referential and qualifying words and phrases, where no contrary intention appears, refer solely to the last antecedent. The last antecedent is "the last word, phrase, or clause that can be made an antecedent without impairing the meaning of the sentence." Thus a provision usually is construed to apply to the provision or clause immediately preceding it.

2 N. Singer, *Sutherland Statutory Construction* § 47.33 (4th ed. 1984) (footnotes omitted) [hereinafter *Sutherland*].

7. Congress is presumed to follow well-accepted rules of grammar absent an expressed intention to the contrary.

> Certainly a legislature is not compelled by any superior force to obey dictionary definitions or the rules of grammar. Except where the contrary is clearly indicated, however, it is a fair assumption that the "authors" of legislation relied on conventional indicia of meaning in shaping their understanding.

Sutherland, supra note 6, at § 45.14.

fringement. The term "patented invention" should not be construed more narrowly—to include only "human drug-related invention"—in subsection (e)(1) than it is in subsection (a). "[A] legislative body generally uses a particular word with a consistent meaning in a given context." *Mills Music, Inc. v. Snyder*, 469 U.S. 153, 165 n.31 (1985) (quoting *Erlenbaugh v. United States*, 409 U.S. 239, 243 (1972)). "[O]nly the most compelling evidence" should persuade the Court "that Congress intended the nearly identical language of . . . two provisions to have different meanings." *Communications Workers of America v. Beck*, 108 S. Ct. 2641, 2653 (1988); *see also Hillsboro Nat'l Bank v. Commissioner*, 460 U.S. 370, 402 (1983); *Roadway Express, Inc. v. Piper*, 447 U.S. 752, 760 (1980); *Sutherland, supra* note 6, at § 46.06.

When Congress used "patented invention," it provided section 271(e)(1) with the most explicit badge of broad scope that could be supplied by the Patent Act. 35 U.S.C. §§ 100-376 (1982 & Supp. I 1983 - Supp. V 1987), *as amended by* Pub. L. No. 100-670, 102 Stat. 3971 (1988). This Court has rejected attempts to avoid the statutory definition of section 101. *Parker v. Flook*, 437 U.S. 584, 590 (1978) ("patentable subject matter under § 101 is not 'like a nose of wax which may be turned and twisted in any direction . . . .'").

"Absent legislative intent to the contrary, or other evidence of a different meaning, legal terms in a statute are presumed to have been used in their legal sense." *Sutherland, supra* note 6, at § 47.30 (footnotes omitted). Congress chose a broad statutorily defined term, then modified it with a highly specific adjacent parenthetical. It defies statutory construction principles to suppose Congress also intended the remote word "drugs" to modify

"patented invention" in order to make it reflect only a portion of its accepted statutory meaning.

B. The Federal Food, Drug, And Cosmetic Act Is "A Federal Law Which Regulates The Manufacture, Use, Or Sale Of Drugs"

1. The Language Of Section 271(e)(1) Is Unambiguous

The plain language of section 271(e)(1) exempts the testing of patented inventions under any "Federal law which regulates . . . drugs." The FD&C Act is such a law. It provides the authority for the FDA to prescribe rigorous testing regimes for drugs and medical devices. Another Federal law which regulates drugs is the PHS Act.[8] *See* 35 U.S.C. § 156(f)(1)(b) and (f)(2).

Having established that medical devices are within the ambit of the broad phrase "patented invention," it is now apparent that the second condition of the statute is fulfilled by FDA testing of medical devices. All such testing is conducted under statutory provisions of the FD&C Act, a law which regulates, among other things, the manufacture, use, and sale of drugs. Although Lilly does not and cannot dispute those facts, it offers a number of arguments that do not address the text of section 271(e)(1) apart from its reference to "drugs."

Section 271(e)(1) is argued to be limited to drugs because drugs are the only products mentioned by name. Pet. Br. 16. According to Lilly, Congress' reference to "Federal law which regulates . . . drugs" does not specify

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8. The PHS Act gives the FDA statutory authority to regulate human biological products, which are a subset of human drugs having a biological as opposed to a chemical origin. 42 U.S.C. §§ 262-63; 21 C.F.R. § 600 ("Authority" clause); § 600.3(h). That authority is not given by the FD&C Act. *See* 21 U.S.C. § 392(b)(1982).

those federal laws under which testing would be exempt, but rather defines the kinds of products that could be the subject of exempted activities. Pet. Br. 21. That conclusion is in hopeless conflict with the words of the statute.

Lilly's assertion (Pet. Br. 16) that Congress could not have meant the phrase "Federal law which regulates . . . drugs" to mean the FD&C Act, because Congress would have just referred to that Act by name, is wrong because it incorrectly assumes that the FD&C Act was the only statute that Congress intended to describe in the quoted passage. But the human biologicals regulated under the PHS Act form a subset of "human pharmaceuticals" (note 8, *supra*) that even Lilly concedes can be tested under section 271(e)(1). Pet. Br. 24. Thus, it is not "odd" (Pet. Br. 10-11) that Congress chose the language it used in section 271(e)(1). The language was intended to describe several laws that Congress had expressly referred to in sections 156(f)(1) and (2) to define *all* products, i.e., drugs, devices and food and color additives,[9] which could trigger patent extension. The chosen language of section 271(e)(1) efficiently embraces the statutes requiring testing and elsewhere acknowledged in the DPC-PTR Act.

Although presented under the banner of "plain language," Lilly's argument fails to respect the language of the statute. If the "Federal law" clause is such an awkward way to describe the FD&C and PHS Acts that this Court should search for an alternative meaning, Lilly proposes no alternative that is faithful to the text.

9. Lilly is incorrect that the products subject to patent extension are defined only in parts (A) and (B) of section 156(f)(1). Section 156(f)(2) which identifies the FD&C Act and the PHS Act is essential to identify the "products" which can result in patent extension.

The statute refers to "a Federal law which regulates . . . drugs," but Lilly would transform the supposed awkwardness of that phrase into a license to ignore the syntax of the statute and to read it as not referring to a set of laws at all.[10] In fact, the language efficiently describes the set of federal laws under which the testing must take place (those that regulate drugs), rather than the set of products (drugs) that must be tested under some federal law.[11]

Because section 271(e)(1) unambiguously refers to the type of "law" under which testing must take place, Lilly makes an isolated argument (Pet. Br. 10) that "law which regulates . . . drugs" means only section 355 of the FD&C Act. 21 U.S.C. § 355 (1982 & Supp. V 1987). That section defines the pre-market approval testing regimen for human drugs. The argument cannot be reconciled with the terms of section 271(e)(1).

10. The different definitions of drugs and devices in the FD&C Act (Pet. Br. 14) are irrelevant because the same law, the FD&C Act, regulates both. Courts "must give effect, if possible, to every word of the statute." *Bowsher v. Merck & Co.*, 460 U.S. 824, 833 (1983). The "operative language" (Pet. Br. 21) is *every word* of the statute, not the single word "drugs." The cases cited by Lilly at Pet. Br. 16 are inapposite. The construction advocated by Medtronic does not ascribe similar meanings to the different phrases in section 271(e)(1) since the "Federal law" clause encompasses laws in addition to the FD&C Act.

11. Contemporaneously with its original passage, one commentator noted that the last clause was broader than just the FD&C Act:

> Section [271(e)(1)] provides that it shall not be an act of infringement to make, use or sell a patented invention solely for uses reasonably related to the development and submission of information *under a federal law which regulates the manufacture, use or sale of drugs*. Not *under the Food, Drug and Cosmetic Act* or not *solely to gain an ANDA or NDA*, but *under any federal law* which regulates the manufacture, sale or use of a drug.

Krulwich, *Statutory Reversal of Roche v. Bolar: What You See Is Only the Beginning of What You Get*, 40 Food Drug Cosm. L.J. 519, 524 (1985) (emphasis in original).

Section 271(e)(1) as originally passed contained a parenthetical excluding "new animal *drug*[*s*]" and "veterinary biological product[s]" from the exemption. But animal *drugs* are not regulated under section 355 of the FD&C Act but rather under section 360b. 21 U.S.C. § 360b (1982 & Supp. V 1987), *as amended by* Pub. L. No. 100-670, 102 Stat. 3971 (1988). If "law" meant only section 355, there would have been no need to use the parenthetical to exclude those products from section 271(e)(1).

Lilly also argues that the reference to "law" in section 271(e)(1) designates sections and not Acts because Congress would not use "shorthand" to designate the entire FD&C Act as a "law which regulates . . . drugs." Pet. Br. 15. But there is no reason why Congress would have been so obscure as to use the general language of section 271(e)(1) to identify one specific section among the many sections of the FD&C Act that regulate drugs. It is far more sensible to read the broad phrase "Federal law which regulates . . . drugs" to mean entire enactments such as the FD&C Act rather than *one* of its many drug-related sections.[12]

12. Other legislation referring to "Federal law" has been construed to refer to overall statutory enactments. For example, under 15 U.S.C. § 2608(a) (1988), the EPA may allow another agency to handle a toxic substance if "risk [from the toxic substance] may be prevented or reduced to a sufficient extent by action taken *under a Federal law* not administered by the [EPA]." (Emphasis added). The Ninth Circuit recently interpreted that section and equated "Federal laws" with broad enactments: "The legislative history cited by Alyeska indicates that Congress was concerned about laws administered by other regulatory agencies rather than forcing the EPA to 'pigeonhole' investigations under particular statutes." *EPA v. Alyeska Pipeline Serv. Co.*, 836 F.2d 443, 447 (9th Cir. 1988). *See also Environmental Defense Fund v. EPA*, 598 F.2d 62, 77 (D.C. Cir. 1978) ("Federal law" considered to encompass other statutes and Acts).

Statutory construction must begin with the language to which a majority of the members of both Houses of Congress could agree, because the legislative purpose is assumed to be expressed through the ordinary meaning of the words used.

> In cases of statutory construction we begin, of course, with the language of the statute. *Southeastern Community College v. Davis*, 442 U.S. 397, 405 (1979). And "unless otherwise defined, words will be interpreted as taking their ordinary, contemporary common meaning." *Perrin v. United States*, 444 U.S. 37, 42 (1979). We have also cautioned that courts "should not read into the patent laws limitations and conditions which the legislature has not expressed." *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199 (1933).

Diamond, 447 U.S. at 308.

Again and again, this Court has sounded the same theme: the most reliable method of carrying out the intent of Congress is to give careful attention to the statutory text, and not to assumptions about congressional "intent" divorced from statutory text.[13] Careful attention to the

13. *See, e.g., Pavelic & LeFlore v. Marvel Entertainment Group*, 58 U.S.L.W. 4038, 4039 (1989) ("Our task is to apply the text, not to improve upon it."); *Northbrook Nat'l Ins. Co. v. Brewer*, 110 S. Ct. 297, 301 (1989) ("We cannot doubt that Congress meant what it said."); *Bourjaily v. United States*, 483 U.S. 171, 178 (1987) ("It would be extraordinary to require legislative history to *confirm* the plain meaning of" a statute.); *United States v. James*, 478 U.S. 597, 604 (1986) ("We assume that the legislative purpose is expressed by the ordinary meaning of the words used."); *Mills Music*, 469 U.S. at 164 ("In construing a federal statute it is appropriate to assume that the ordinary meaning of the language that Congress employed 'accurately expresses the legislative purpose.'"); *Garcia v. United States*, 469 U.S. 70, 78 (1985) ("We are not willing to narrow the plain meaning of . . . a . . . statute on the basis of a gestalt judgment as to what Congress probably intended."); *United States v. Locke*, 471 U.S. 84, 95-96 (1985) ("[T]hat Congressmen typically vote on the language of a bill, generally requires us to assume that the 'legislative purpose is expressed by the ordinary meaning of the words used.'");

language of section 271(e)(1) can produce only one result:[14] "law which regulates . . . drugs" identifies a set of laws that includes the FD&C Act. Medtronic's medical devices were tested under the FD&C Act, and they therefore come within the terms of the statute.[15]

2. The 1988 Amendments Confirm That Congress Used The "Law Which Regulates . . ." Construction To Identify Entire Acts Of Congress

The 1988 Amendments conclusively establish that "Federal law which regulates . . . drugs" was meant to include the entire FD&C Act and PHS Act. Those Amendments broadened the exemption of section 271(e)(1) by amending the "law which regulates" clause in section 271(e)(1) to refer to "law which regulates . . . drugs or veterinary biological products." Lilly argues that the addition of "veterinary biological products" is evidence that Congress

New England Power Co. v. New Hampshire, 455 U.S. 331, 343 (1982) (Courts have no authority to rewrite legislation based on "mere speculation as to what Congress 'probably had in mind.'").

14. Senator Metzenbaum's admonition to those who would be construing the DPC-PTR Act is enlightening:

> [T]here are many people asking what this bill is all about; what it means; how do you interpret it. Let me say, for one, that I interpret it in only one manner. Nobody can change the language of the legislation. It speaks for itself. So notwithstanding anybody who may feel that they can interpret the language of this legislation in one way or another, I want the courts to understand that the legislation speaks for itself and the interpretation which anyone may make on the floor does not really add anything to that interpretation.

Text of S. 2926 and Floor Remarks, *reprinted in* 28 Pat. Trademark & Copyright J. (BNA) 435, 447 (1984).

15. Judge Newman termed the panel's decision "judicial legislation" (Pet. App. 12a) while advancing an all too apparent misreading of the statute. Pet. App. 10a. Section 271(e)(1) is not "limited to the 'manufacture use or sale of drugs'" as Judge Newman suggested. *Id.* Neither Judge Newman nor Lilly ever squarely confronts the fact that "drugs" modifies "law" and nothing else.

named in section 271(e)(1) all the products that it wished to make eligible for exemption under that statute. Pet. Br. 14 n.8. In fact, Congress did nothing of the kind.

Interstate commerce in veterinary biological products is regulated under the Virus-Serum-Toxin Act. 21 U.S.C. §§ 151-58 (1982 & Supp. I 1983 - Supp. V 1987); *Grand Laboratories, Inc. v. Harris*, 660 F.2d 1288 (8th Cir. 1981), *cert. denied*, 456 U.S. 927 (1982). Thus, the addition of "veterinary biological products" to the "law which regulates" clause means that testing *under a law that regulates veterinary biological products* (the Virus-Serum-Toxin Act) is exempt. The 1988 Amendments were not Congressional attempts to name all exempt products in section 271(e)(1).

Furthermore, the amendments disprove Lilly's assertion that the "law which regulates" clause refers to (unspecified) discrete individual sections of Acts of Congress. There can be no doubt that the reference to "law which regulates . . . veterinary biological products" in the amended section 271(e)(1) refers to the entire Virus-Serum-Toxin Act.[16] In the simultaneous parallel amendments to the patent extension statute, 35 U.S.C. § 156, Congress made several specific references to products and applications "subject to" or "under" "the Virus-Serum-Toxin Act." *See* 35 U.S.C. § 156(d)(2)(A)(i), (d)(2)(B)(i), (g)(5)(B)(i), (g)(5)(B)(ii). Nonetheless, Congress chose the more generic expression in section 271(e)(1).

16. The Virus-Serum-Toxin Act, is the same as "the Act of March 4, 1913" which appears in the parenthetical of section 271(e)(1). The fact that Congress identified that Act in an early part of the section, and referred to the same law as one which "regulates . . . veterinary biological products" at the end, further refutes Lilly's argument that Congress' cite of the FD&C Act at one part of the section would compel repetition of that cite to identify the "law."

3. The Sections And Subsections Of The FD&C Act That Regulate Drugs Also Regulate Devices

Medtronic has demonstrated that Congress used the phrase "law which regulates . . . drugs or veterinary biological products" in section 271(e)(1) to designate broad enactments. But even if the word "law" should mean an individual section rather than an entire Act (Pet. Br. 10), Medtronic still would prevail. The structure of the FD&C Act does not, for the most part, contain discrete and segregable "device provisions" as Lilly suggests. Pet. Br. 15. The statement that "[d]rugs and devices are regulated under entirely different statutory provisions" (Pet. Br. 14-15) is true only in one respect: sections 355 and 360 outline the respective testing requirements for new drugs and new medical devices. But the general prohibition against introducing a new drug or device into commerce without meeting those testing requirements, and thus their "regulation," is contained in a single section—section 331. 21 U.S.C. § 331 (1982 & Supp. V 1987). "The heart of the enforcement provisions of the FD&C Act is [Section 331], which enumerates the acts prohibited by the statute." R. Merrill & P. Hutt, *Food and Drug Law* 661 (1980).

Both drugs and medical devices are regulated by section 331 of the FD&C Act. It contains subsections that vary in scope and cut across distinctions among food, drugs, devices and cosmetics. The section directs the reader to other sections of the Act, which in turn detail the procedural requirements that must be met to qualify different products and thus overcome the prohibition against introducing them into commerce.

For illustration, consider the following subsections of section 331. Subsection 331(a) prohibits placing in

interstate commerce "any food, drug, device, or cosmetic that is adulterated or misbranded." Subsection 331(d) prohibits placing any article in interstate commerce in violation of section 344, which provides food regulation, or section 355, which provides the basic regulation of new drugs. Subsection 331(e) prohibits the failure to maintain and permit access to certain records required to be kept under subsections 355(i) or (j), which regulate clinical test reports for new drugs, under subsections 360b (j), (l) or (m), which deal with new animal drugs, or under subsection 360e(f), which is directed to developing protocols and reports on medical devices. Subsection 331(p) prohibits the failure to register or provide certain information in accordance with section 360 and specific subsections of section 360, which provide the overall registration regulation for both drugs and medical devices.

The *subsections* of section 331 that regulate devices also regulate drugs. Subsection 331(p) requires submission of information on drugs under subsection 360(j). It also requires submission of information under subsection 360(k), which specifies the tests that must be submitted before introduction of devices into interstate commerce. Subsection 331(e) regulates and requires the development and submission of information and does so for human drugs, animal drugs, and medical devices. Medtronic's development and submission of information was done in compliance with subsections 331(p) and 331(e), which, as part of section 331, "regulate[ ] the manufacture, use, or sale of drugs."

No matter how narrowly Lilly tries to read "Federal law," medical device testing is done under a "Federal law which regulates . . . drugs." Test information on medical devices is developed and submitted under an *Act* of Congress that regulates drugs, the FD&C Act; a *section*

that regulates drugs, section 331; and *subsections* that regulate drugs, subsections 331(p) and 331(e). It follows, then, that the development and submission of information on medical devices qualifies for the protection of section 271(e)(1) as much as the development and submission of information concerning drugs. Lilly's view that devices are excluded from section 271(e)(1) would require parsing sentences and even clauses within subsections to determine the activity to which the exemption applies, a process that Congress' language does not contemplate. The compulsion of the statutory language should end the matter. *Ron Pair*, 109 S. Ct. at 1030.

II. THE PLAIN MEANING IS SUPPORTED BY THE STATUTORY CONTEXT OF THE LEGISLATIVE PACKAGE CONTAINING SECTION 271(e)(1)

The analysis of the statutory language advanced above is dispositive. It is reinforced and illuminated by a review of the companion provisions in Title II of the DPC-PTR Act, which utterly contradict Lilly's arguments on the legislative intent.

As discussed at page 2, *supra*, the DPC-PTR Act effected two major amendments to the patent statute. Section 156 made patent extensions available to product or process patentees who experienced delay in commercializing a "human drug product"[17] or "[a]ny medical device, food additive or color additive subject to regulation under the [FD&C Act]." In the context of that patent term extension, Congress simultaneously created the exemption in section 271(e)(1) for all "patented inventions" (except for animal drugs and veterinary biological products) when employed "for uses reasonably

17. Under section 156 human drug products corresponded to "a new drug, antibiotic drug, or human biological product" as defined in the FD&C Act and the PHS Act. *See* 35 U.S.C. § 156(f)(2)(A).

related to the development and submission of information under a Federal law which regulates . . . drugs."

Because "[s]tatutory construction . . . is a holistic endeavor," the meaning of a statute should be regarded as clear when "only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law." *United Savings*, 108 S. Ct. at 630. Construing section 271(e)(1) in the context of the DPC-PTR Act reveals an unmistakable symmetry between sections 156 and 271(e)(1). Because medical devices are covered by section 156, they should be covered by section 271(e)(1) as well.

A. Congress Intended That Sections 156 And 271(e)(1) Have The Same Scope

The objectives of the DPC-PTR Act were to remedy the negative effects of FDA regulatory delays on achievement of the goals of the patent system. Those goals were to stimulate innovation by rewarding inventors with "the right to be free from competition in the practice of the invention" for a limited time, *Mercoid Corp. v. Mid-Continent Investment Co.*, 320 U.S. 661, 665 (1944), and to make the invention immediately available to the public upon the patent's expiration.[18]

Prior to passage of the DPC-PTR Act, FDA regulatory delays and the decision in *Roche Prods., Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir.), *cert. denied*, 469 U.S. 856 (1984), combined to produce both *de facto* reductions and *de facto* extensions in patent

18. An exclusive enjoyment is guaranteed [the inventor] for seventeen years, but upon expiration of that period, the knowledge of the invention inures to the people who are thus enabled without restriction to practice it and profit by its use.
Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 109 S. Ct. 971, 977 (1989) (quoting *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 186-87 (1933)).

terms. The effects of regulatory delay, therefore, were to shift the effective patent term in time. But the intrusion of the regulatory process made the beginning and end of the effective term unpredictable and indefinite.

Sections 156 and 271(e) were intended to strike a balance between the patentee's *de facto* loss of patent term and the *de facto* extension of that term that resulted from FDA regulatory delay. The remedy chosen by Congress was to grant patentees a definite extension of their patent term up to five years upon a proper showing. In turn, Congress chose to eliminate any *de facto* extension of patent term.

The House Energy and Commerce Committee made it clear that section 271(e)(1) was designed to eliminate those *de facto* extensions:

> Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. *That limited time should be a definite time and, thereafter, immediate competition should be encouraged.*
>
> * * *
>
> [E]xperimental activity does not have any adverse economic impact on the patent owner's exclusivity during the life of a patent, but *prevention of such activity would extend the patent owner's commercial exclusivity beyond the patent expiration date.*
>
> * * *
>
> [The provisions of section 156] permit the extension of the term of a patent for a definite time provided certain conditions are met. *There should be no other direct or indirect method of extending patent term.*

H.R. Rep. 98-857(I), *supra* p. 7, at 45-46 (emphasis added).

Those statements of Congressional intent are totally inconsistent with the notion that Congress wanted to limit the exemption of section 271(e)(1) to drugs. Without doubt, Congress intended broadly to substitute the definite patent extension provided by section 156 for the *de facto* extension which results if FDA-mandated testing of those products can be deemed patent infringement. To hold otherwise would be to postulate a Congressional objective to prefer medical devices and other FDA-regulated inventions to drug inventions. Section 271(e)(1) was designed to preclude indefinite *de facto* extensions for *all* products entitled to statutory extensions under section 156.[19] To accomplish that purpose the scope of products affected by section 271(e)(1) must be the same as those affected by section 156.[20]

A Congressional grant of term extension to devices without an accompanying exemption would be inconsistent with the marked congressional restraint otherwise evident during consideration of the DPC-PTR Act. For example, Congress decided to limit the maximum term of a possible extension to five years, which was significantly less than the average ten-year regulatory compliance period for the average new drug invention. 130

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19. The importance of that objective was emphasized by one commentator involved with the legislative process: "Congressman Waxman took the position that, while a pioneer is entitled to his patent, perhaps even extended, when the patent expires, competition should begin, not delayed by the need to perform studies to satisfy the FDA." Lourie, *Patent Term Restoration*, 66 J. Pat. Off. Soc'y 526, 534-35 (1984) [hereinafter Lourie].

20. The Federal Circuit recognized that section 271(e) should have the same scope as section 156 so as to preclude any one product from receiving both direct and indirect extensions. The court stated that "[n]o persuasive reason is suggested why Congress would create an exception with respect to those activities for drugs only, *particularly as medical devices receive the benefit of the companion patent term restoration legislation.*" *Eli Lilly & Co. v. Medtronic, Inc.*, Pet. App. 7a (emphasis added).

Cong. Rec. H8706 (daily ed. Aug. 8, 1984). That cautious legislative approach to term extension simply does not harmonize with a legislative intent to grant medical device inventions a preferred status vis-à-vis drug inventions.

As the frontiers of medical technology expand, the treatment of life-threatening diseases probably will involve the development of more complex and risk-laden devices. It is logical to assume that the level of FDA scrutiny will increase. If the "secondary patent" or "regulatory patent" is allowed to exist for medical devices—contrary to Congress' expressed intent to eliminate "direct and indirect" means of patent extension other than section 156—it will become an even greater impediment to market entry in the future.

In the DPC-PTR Act, Congress granted patent term extension rights to human drugs and biologicals, medical devices, and food and color additives. To fulfill its objective of eliminating indirect patent term extension for those products, it was required in section 271(e)(1) to exempt regulatory testing of those products from infringement.[21] Maintenance of the internal balance within the DPC-PTR Act requires that the exemption apply to medical devices.

B. The Legislative Evolution Of Section 271(e)(1) Shows That Congress Consistently Maintained Congruency With Section 156

When the earliest version of the DPC-PTR Act was reported out of the House Subcommittee on Health and

21. Section 271(e)(1) will have little effect on food and color additives or cosmetics. Cosmetics do not require premarket approval testing. Additives are tested typically by the first manufacturer to establish regulations for their use. 21 U.S.C. § 348(b) (1982). Subsequent competitors are required only to satisfy those regulations, § 348(a)(2) (1982), and would not face a significant delay to market from a "regulatory patent" after patent expiration.

the Environment, the bill provided for term extension for inventions subject to FDA regulation.[22] H.R. Rep. 98-857(I), *supra* p. 7, at 16-17, 37-47. Simultaneously, the companion FDA-testing exemption was available for *any* patented invention provided the use was "reasonably related to the development and submission of information under a federal law which regulates . . . drugs." *Innovation and Patent Law Reform: Hearings Before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the House Comm. on the Judiciary*, 98th Cong., 2d Sess. 630-49 (1984) [hereinafter *Innovation Hearings*].

Before the final amendments to the DPC-PTR Act in September 1984, Congress decided to address patent extensions for animal drugs and veterinary biological products in the legislative subcommittee that deals with agricultural subjects.[23] To uncouple the animal products from the pending DPC-PTR Act, Congress expressly eliminated animal drugs and veterinary biological products from the list of products in section 156 that could trigger patent term extension. *Compare* text of H.R. 3605 found in *Id.* at 600-49 *with* text of H.R. 3605 found at 130 Cong. Rec. H9150 (daily ed. Sept. 6, 1984). Patent term extension then remained available only for human drugs, including human biological products, medical devices, and food and color additives. H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 7 (1984) [hereinafter H.R. Rep. 98-857(II)]. Simultaneously, Congress inserted the parenthetical exception after "patented invention" in the pending section 271(e)(1). S. 2926, 98th Cong., 2d Sess., 130 Cong. Rec. S10512 (daily ed. Aug. 10, 1984).

22. Patent term extension at this stage was proposed for human and animal drugs (including human and animal biological products), medical devices, and food and color additives.

23. Lourie, *supra* note 19, at 540.

After 1984, Congress sought to maintain the congruency. In 1986, a proposed bill sought to amend section 156 to provide term extension for all animal drugs and veterinary biological products. At that point, the proposed amendment to section 271(e)(1) would have made the same products exempt by deleting the entire parenthetical expression in that section. S. Rep. No. 448, 99th Cong., 2d Sess. 10-11 (1986). But the genetic engineering industry objected and sought to exclude genetic engineering inventions from the exemption of section 271 (e)(1). The result was that in the 1988 Amendments the total congruency was preserved. The exemption for genetically engineered animal drugs and veterinary biologicals was withdrawn from section 271(e)(1) and patent term extension for the same products simultaneously was removed from section 156. 134 Cong. Rec. H9785 (daily ed. Oct. 6, 1988) (statement of Rep. Waxman).

Those complementary actions provide an unmistakable signal that section 156 and section 271(e)(1) were designed to be congruent in scope. Had Congress intended to exclude devices from section 271(e)(1). it would have expressly added medical devices to the exclusionary parenthetical. The inevitable conclusion is that the legislative intent was to include devices in section 271(e)(1).

C. Section 271(e)(1), Unlike Section 271(e)(2), Is Not Limited To Generic Drug Applications

Section 271(e)(1)—at issue here—defines certain acts *not* to be patent infringement, whereas section 271(e)(2) states that the submission of certain kinds of FDA applications *is* patent infringement. Because section 271(e)(2) refers to certain kinds of applications that can be submitted only for generic drugs, Lilly and its *amici* assert

that it must follow that section 271(e)(1) applies only to generic drugs. There is, however, no basis for that inference.

Section 271(e)(2) prohibits the mere filing of an application for expedited approval via ANDA or "paper" NDA procedures—procedures that are available only for generic drugs[24]—with an intent to commercialize a patented product before the expiration of the patent. But filing an application to test a pioneer drug under full NDA procedures is not defined as an act of infringement in section 271(e)(2). Yet Lilly agrees that section 271(e)(1) expressly exempts the testing of pioneer drugs. *See* Pet. Br. 30 n.20. Thus, section 271(e)(1) undeniably is broader than section 271(e)(2), and section 271(e)(2) provides no basis for asserting that section 271(e)(1) is limited to bioequivalency testing of generic drugs.

In the medical device arena there are no provisions, comparable to those for drugs, for abbreviated safety and efficacy testing of medical devices in the class of implantable defibrillators. 21 U.S.C. 360c(a)(1)(C) (1982). Thus, just as there was no need to provide patentees special protection in section 271(e)(2) for pioneer drug testing, there was no need to provide protection in section 271(e)(2) for complete testing of medical devices such as the PCD which requires the most rigorous testing.

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24. The ANDA (abbreviated new drug application) and paper NDA (new drug application) procedures involve shortened and less onerous test requirements than the requirements to qualify a new drug under full NDA procedures. *See* 21 U.S.C. §§ 355(b)(2) and (j). "Pioneer" drugs are new compositions that must pass the most rigorous approval protocols under NDA procedures. Generic drugs are usually chemical copies of a pioneer drug composition; they emerge in large drug markets when the pioneer drug goes "off-patent." The abbreviated ANDA or paper NDA procedures are available to generic manufacturers since there has been significant experience with the pioneer drug.

Lilly's argument that subsection (e)(2) limits subsection (e)(1) has no merit.

D. Section 271(e)(1) Is Not Limited To Generic Bioequivalency Testing

The suggestion that section 271(e)(1) is limited to generic bioequivalency testing is insupportable. Pet. Br. 29. The express language of section 271(e)(1) exempts more than generic bioequivalency testing. Lilly and its *amici* concede that pioneer drug testing is exempted. Pet. Br. 30 n.20; Pfizer Br. 5 n.4; Bristol Myers Br. 16. Use of a patented process reasonably related to preparing or administering a new pioneer drug also is exempt. Most significantly, the language of section 271(e)(1) clearly would exempt the use of a patented device such as an atomizer, if its use is reasonably related to the clinical testing of a generic or new inhalant drug, for example. The exemption of section 271(e)(1) simply is not restricted merely to patented drug inventions used in generic bioequivalency testing but embraces the entire scope of useful patented inventions.[25]

That conclusion is supported by a detailed analysis of the scope of section 271(e)(1). *See* Wheaton, *Generic Competition and Pharmaceutical Innovation: the Drug Price Competition and Patent Term Restoration Act of 1984*, 35 Cath. U.L. Rev. 433 (1986). Professor Wheaton determined that section 271(e)(1) is not

> limited to the compilation of information necessary to submit an ANDA, instead, the statute refers to "any Federal law" regulating the manufacture, use, or sale of drugs. Thus, as the provision is written, it would not be an act of infringement for a manufacturer to conduct tests needed to submit a paper NDA for a generic copy of the new drug, or a full NDA for a use or dosage form not already approved in the pioneer drug's NDA.

Id. at 462. The part of the DPC-PTR Act that matured into section 271(e)(1) never was restricted to bioequivalency testing of generic drugs, or to drugs at all.[26]

25. By the 1988 Amendments, section 271(e)(1) was modified to preclude from the infringement exemption the use of patented genetic engineering processes if used in connection with testing animal drugs. That is was necessary to specifically exclude this one type of patented process from the infringement exemption shows clearly that use of such patented processes for human drugs, as well as use of all *non*-genetic patented processes, are left within the infringement exemption.

III. EXTRINSIC AIDS TO STATUTORY CONSTRUCTION SUPPORT MEDTRONIC'S PLAIN MEANING INTERPRETATION

A. The Public Policy Goals Chosen By Congress Are Best Furthered By According Section 271(e)(1) Its Plain Meaning

The DPC-PTR Act implements specific policy choices made by Congress to encourage innovation and competition in FDA-regulated products. To stimulate innovation, Congress gave patentees of FDA-regulated products patent term extension to restore a period of market exclusivity lost because of FDA delays. To promote free competition upon the patent's expiration, Congress gave competitors the right to do necessary FDA testing during

26. Lilly quotes out of context (Pet. Br. 32) an isolated statement from the legislative history that might seem to suggest that bioequivalency testing was the "only activity" permitted under Section 271(e)(1). *See* Sec. III.B, *infra*. The cited comment was made in response to a proposed amendment by Representative Moorhead that challenged the constitutionality of the section 271(e)(1) exemption on the ground that it was an improper "taking" of property. Representative Moorhead had sought to introduce a waiver provision in the pending patent restoration provision under which the patentee would make a limited waiver permitting generic bioequivalency testing if term extension were sought. The Congressional statement suggesting that "only" bioequivalency testing is permitted was a response to that amendment and represents an understandable lapse in the context of rejecting the "taking" argument. It does not represent the kind of legislative history that can overcome the clearly contrary terms of a statute.

the patent term. Those choices support the construction that section 271(e)(1) exempts testing necessary to secure FDA approval of devices. *See Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 220-21 (1980) (policy choices attributable to Congress can be determinative of statutory construction).

Section 271(e)(1) reflects the policy decision by Congress that public health concerns outweigh a private patentee's interest in preventing the start of FDA testing until the patent expires. Even though generic drugs are merely less expensive copies of existing and available drugs, Congress believed that their prompt introduction upon patent expiration warranted the enactment of section 271(e)(1). Lifesaving devices such as implantable defibrillators face regulatory barriers to market entry as formidable as those faced by drugs. *Contact Lens Mfrs. Ass'n v. FDA*, 766 F.2d 592, 596 (D.C. Cir. 1985), *cert. denied*, 474 U.S. 1062 (1986). The congressional choice in favor of public health is advanced by making device testing exempt in accordance with the plain language of section 271(e)(1) so that *improved* lifesaving devices become available to the public immediately after a patent's term.

Exempting medical device testing under section 271(e)(1) also spurs innovation, an additional goal of Congress in passing the DPC-PTR Act. Unlike generic drug companies, competitors in the medical device industry succeed by providing an improved product, not merely a cheaper one. The pharmacological efficacy of a drug may remain near optimal through the entire patent term. In contrast, most device inventions undergo significant improvement by the end of patent term.[27] As device patents

27. Evidence at trial established that Medtronic's Model 7215 contained features "ideal" for an implantable device designed to treat tachyarrhythmias. J. App. 53-54. Whereas Lilly has had an implantable defibrillator with pacing capabilities under development since prior to trial in March, 1988 (J. App. 58), as of this writing, their commercial device offers only high energy shock therapy. J. App. 69-70. There clearly exist patients for which that traumatic high energy shock therapy is inappropriate. J. App. 50, 65, 71, 75-78. The injunction in this case has affirmatively precluded some patients in the United States from obtaining the best available therapy. J. App. 82-83.

approach the end of their term, the availability of the section 271(e)(1) exemption will advance medical knowledge, benefit public health, and spur innovation to provide superior devices soon after expiration of a patent that otherwise would be broad enough to preclude such development.[28] *Orphan Drug Amendments of 1987: Hearings on H.R. 3349 Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 100th Cong., 2d Sess. 24 (1987) (statement of Commissioner of the FDA) ("For [worthwhile] devices, the public health would not be well served if we were to block innovation through the application of an exclusivity provision that limited even minor improvements.") [hereinafter *Orphan Drug Hearings*]. If the exclusionary effects of the "regulatory patent" can preserve the patentee's exclusivity beyond the date of patent expiration, there is an affirmative disincentive to improve upon the patented device. Competitors will devote resources to areas where there is less impediment to free competition.

Congress did not subordinate section 271(e)(1) to the patentee's interests by tailoring the section to exempt only uses having no effect on the patentee's market. Pet. Br. 30. Although the section exempts typical generic bioequivalency drug testing in which the patented drug is

28. For example, a device such as the Medtronic PCD strives to use the latest in a spectrum of technical disciplines such as microelectronics, microprocessors, and battery technology.

given to healthy volunteers who would not otherwise purchase it, the section also plainly exempts bioequivalency testing when the drug is given to individuals in the patentee's target population because the drug has toxic side effects. Bristol Myers Br. 15 n.21. More significantly, the testing of a new drug on potential patients of the patentee also is permitted. Pet. Br. 30 n.20.

The dominant Congressional purpose was to permit testing during the patent term of the latest medical technology on the limited basis allowed by the FDA so that patent expiration could signal the onset of active competition. H.R. Rep. 98-857(1), *supra* p. 7, at 45-46. In passing the DPC-PTR Act, Congress made the policy judgment that such minor incursion on a patentee's right to exclude and, in a few instances, on its market exclusivity, would not deter innovation since the patentee would receive the balancing benefit of patent term extension.[29]

29. A major device manufacturer with the potential to develop a new device and therapy can obtain a patent extendable to twenty-two years. It simply is not credible that the prospect of some "competition" from others conducting clinical tests near the end of patent term would discourage such innovation. Lilly furnishes a misleading example of an expensive CAT-scan device which would seriously damage the patentee's market if sales for FDA testing were exempt from infringement. Pet. Br. 30. But CAT-scan devices are Class II medical devices and normally do not undergo the type of testing that would enable a competitor to avail itself of the testing exemption of section 271(e)(1). *See* 21 C.F.R. §§ 892.1740 & 1750; 21 U.S.C. § 360c(a)(1)(B). In fact over 90% of medical devices brought to market do not require testing. *See, e.g.*, Kahan, *FDA Regulations of Drug-Device Combinations*, Medical Device and Drug Industry, 58, 60 (Oct. 1989) [hereinafter Kahan].

Concerns that Investigational Review Boards ("IRBs") might be used by manufacturers as a subterfuge (Neuromedical Br. 5) to gain commercial advantage are unfounded. The composition and procedures of IRBs are strictly defined. 21 C.F.R. §§ 56.107-09, 111. Further, testing of any device significantly benefitted by section 271(e)(1) (21 C.F.R. § 812.3(m) & 21 U.S.C. § 360c(a)(1)(C)) is supervised by both the FDA and each IRB. 21 C.F.R. §§ 812.66, 812.30(a).

B. The Legislative History Supports The Conclusion That Congress Chose To Exempt All Products That Undergo FDA Testing

In enacting section 271(e)(1), Congress wanted to promote free competition in FDA-regulated products immediately upon patent expiration.

> Article 1, Section 8, Clause 8 of the Constitution empowers Congress to grant exclusive rights to an inventor for a limited time. *That limited time should be a definite time and, thereafter, immediate competition should be encouraged.*
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> [The provisions of section 156] permit the extension of the term of a patent [on certain FDA-regulated products] for a definite time provided certain conditions are met. *There should be no other direct or indirect method of extending patent term.*

H.R. Rep. 98-857(1), *supra* p. 7, at 45-46 (emphasis added).

Congressional statements discussing the projected effects of the legislation on the drug industry (Pet. Br. 22-23) do not evidence a narrower objective. This Court has observed that "congressional discussion [which] focused on the needs of female members of the work force rather than spouses of male employees . . . does not create a 'negative inference' limiting the scope of the Act to the specific problem that motivated its enactment." *Newport News Shipbuilding & Dry Dock Co. v. EEOC*, 462 U.S. 669, 679 (1983). *See also United States v. Turkette*, 452 U.S. 576, 591 (1981). Similarly here, the mere fact that generic drug manufacturers were the catalyst for passage of section 271(e)(1) does not indicate that they were its only beneficiary.

The flaw in Lilly's interpretation of the legislative history of section 271(e)(1) can be highlighted by reference to the legislative history of section 156. Despite the fact that section 156 expressly encompasses devices,[30] its entire legislative history suggests that it is solely concerned with drugs. *See* App. A. There is no mention of the problems or benefits that section 156 provides medical device manufacturers. Even in the history of the 1988 amendments, committees of Congress continued to refer consistently to section 156 as a bill to benefit the drug industry even though devices are expressly covered. *See* App. B. If Lilly's citations at Pet. Br. 23-24 prove that devices were excluded from section 271(e)(1), the same reasoning would compel the Court to draw the manifestly incorrect conclusion that Congress did not provide patent term extension for devices in section 156.

Congressional focus on drugs in discussing sections 156 and 271(e)(1), even while *legislating* more broadly, was understandable. Section 271(e)(1) was intended to overrule the Federal Circuit's decision in *Roche*, 733 F.2d 858. The *Roche* case involved generic drugs, so members of Congress naturally spoke about generic drugs.

It also is not difficult to understand the presence of competing drugs interests, and the absence of competing device interests, in the legislative debates. The drug industry is composed of pioneer drug manufacturers and generic drug manufacturers which had directly competing interests at stake in the DPC-PTR Act. The device industry was and is not so divided; every company strives to be an innovator. *Orphan Drug Hearings*, *supra* p. 33, at 23 (The Commissioner of the FDA said "unlike drugs, carbon copies of devices are not the rule"). *See also* Smith, *Device Pre-market Approval: Lessons from the Drug Approval Experience*, 38 Food Drug Cosm. L.J. 4, 11 (1983). Regulated implantable devices such as pacemakers, heart valves, and the PCD are constantly evolving products of the latest technology, and are not "generic" in the same sense as an off-patent drug. Furthermore, when the DPC-PTR Act was passed, the effects of testing delays were not yet as apparent to the device makers as they were to drug manufacturers.[31] The absence of device manufacturers in the legislative history surrounding sections 156 and 271(e)(1) is thus not surprising, nor does it indicate that the latter section excludes medical devices.

More generally, the absence of reference to devices in the legislative history of section 271(e)(1) is unpersuasive because it simply "is not the law that a statute can have no effects which are not explicitly mentioned in its legislative history . . . ." *Pittston Coal Group v. Sebben*, 109 S. Ct. 414, 420-21 (1988). This Court repeatedly has interpreted statutes in accordance with their terms, even when to do so would have effects not mentioned in the legislative history. *See, e.g., Mansell v. Mansell*, 109 S. Ct. 2023, 2030 (1989); *Ron Pair*, 109

30. Reference to devices was required in Section 156 because the calculation of the *length* of extension available depends upon the nature of the "product" as a result of the differences in testing delays incurred by each. *See* 35 U.S.C. §§ 156(f)(1) and 156(g)(3).

31. Although device regulating power was granted to the FDA in 1976, broad scale implementation did not occur for years. Adler, *supra* note 1, at 520; Kahan, *supra* note 29, at 292; Benson, *A Look at the Progress of the Food and Drug Administration's Medical Device Program*, 40 Food Drug Cosm. L.J. 95, 99-100 (1985) (Dep. Dir. of the Center for Devices and Radiological Health). It had taken seventeen years for the drug industry to move Congress for relief from lengthy FDA testing requirements. The statutory change requiring drug makers to undertake testing to obtain FDA approval occurred in 1962, but the first patent term extension bill was introduced in 1979. H.R. 3589, 96th Cong., 1st Sess. (1979).

S. Ct. at 1031 & n.6; *Sedima, S.P.R.L. v. Imrex Co.*, 473 U.S. 479, 499-500 (1985); *Newport News*, 462 U.S. at 679. "This Court frequently has observed that a statute is not to be confined to the 'particular application[s] . . . contemplated by the legislators.' This is especially true in the field of patent law." *Diamond*, 447 U.S. at 315-16 (citations omitted). Congressional focus on drugs rather than devices does not mean that statutory text with a broader reach can be disregarded.[32]

Legislative history may have a role to play in clarifying ambiguities on the face of a statute. It is not, however, proper to use legislative history in an effort to *create* ambiguity where none exists. *Pierce v. Underwood*, 108 S. Ct. 2541, 2550-51 (1988); *Burlington N. R.R. v. Oklahoma Tax Comm'n*, 481 U.S. 454, 461 (1987); *James*, 478 U.S. at 604-05. Section 271(e)(1) plainly makes it not an act of patent infringement to make, use or sell *any* "patented invention" (with exceptions that do not apply here) for submissions "under a Federal law which regulates . . . drugs." Any language in the legislative history which implies that the statute does not reach some patented inventions used for the submission of information under such a law (*see supra* note 26) is in conflict with the plain terms of the statute and is entitled to no weight. *Davis v. Michigan Dep't of Treasury*, 109 S. Ct. 1500, 1504 n.3 (1989) ("Legislative history is irrelevant to the interpretation of an unambiguous statute.").

32. Alternatively, section 271(e)(1) could be viewed in its role as remedial legislation to solve the conflicts between the FDA approval process and the patent system. As such the section should be "literally construed to suppress the evil and advance the remedy." *Sutherland*, *supra* note 6, at § 60.01. Thus, even if Congress corrected the regulatory patent problem believing it did so only for drugs, when similar problems became apparent with respect to medical devices, the same remedy should be applied by the courts to the device problem.

To disprove the plain meaning of section 271(e)(1), Lilly must make an affirmative showing of an intent to exclude devices from the scope of section 271(e)(1). Statutory language that is unambiguous "must ordinarily be regarded as conclusive" in the absence of "a clearly expressed legislative intent to the contrary." *Turkette*, 452 U.S. at 580. Without a clear indication that Congress focused directly on this issue, "there is no basis for reading into its actions an intent to modify the plain meaning of the words" in the law as enacted. *Diamond*, 447 U.S. at 314. At most Lilly has shown that Congress intended to *include drugs*; it has not shown an intent to *exclude devices*.

C. Congress Decided That The Public Interest In Free Competition Is More Important Than A Patentee's Interest In Indirect Patent Term Extension

Section 271(e)(1) is a statutory recognition of two well-accepted principles: that the public interest supersedes the patentee's right to profit, and that the patent system is a strictly circumscribed exception to free competition. Enforcement of those principles is at least as important in the case of devices as drugs.[33] Exempting device testing opens new therapies and encourages innovation in rapidly evolving technologies.

The patentee's right to exclusivity is not all-encompassing. As this Court noted in *Kendall v. Winsor*, 62

33. Lilly argues that permitting device testing would represent an unconstitutional "taking" from device patentees. Pet. Br. 31-32. But that argument is grounded on the false premise that the permitted drug testing under section 271(e)(1) is restricted to bioequivalency testing. *See* Sec. II. D, *supra*. Moreover, Congress had reasons that apply equally to drugs and devices that section 271(e)(1) did not represent a "taking." H.R. Rep. 98-857(II), *supra* p. 27, at 27-30.

U.S. (21 How.) 322, 328 (1859), "that the limited and temporary monopoly granted to inventors was never designed for their exclusive profit or advantage; the benefit to the public or community at large was another and doubtless the primary object in granting and securing that monopoly."

Thus, this Court has defined the patentee's right as "a right to be free from competition in the practice of the invention." *Mercoid*, 320 U.S. at 665; *see also* W. Robinson, *The Law of Patents for Useful Inventions* § 898 (1890). Such freedom from competition is generally disfavored in the law and is granted only to the extent necessary to secure countervailing benefits. *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 530-31 (1980). There is a "congressional understanding" that "free exploitation of ideas will be the rule." *Bonito Boats*, 109 S. Ct. at 978; *see also Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230-31 (1964) ("the patent system is one in which uniform federal standards are carefully used to promote invention while at the same time preserving free competition."); *Sony Corp. of America v. Universal City Studios*, 464 U.S. 417, 429 (1984) (The monopoly privileges of patent and copyright are "intended to motivate the creative activity of authors and inventors . . . and to allow public access to the products of their genius after the limited period of exclusive control has expired."). Section 271(e)(1) evinces a Congressional choice to apply that policy to products requiring FDA testing.[34]

34. The preference for immediate competition long has been an integral element of the patent system. In *Pennock v. Dialogue*, 27 U.S. (1 Pet.) 1, 19 (1829) this Court stated:

> [T]he main object [of the patent system] was 'to promote the progress of science and useful arts;' and this could be done best by giving the public at large a right to make, construct, use, and vend the thing invented, *at as early a period as possible;* having a due regard to the rights of the inventor.

(Emphasis added).

A conclusion that it covers medical devices supports that Congressional goal.

Lilly is asking that its patent monopoly be effective to preclude FDA testing until the end of its extended patent term. That is similar to the respondent's request in *Deepsouth*, 406 U.S. at 518, and should be answered in the same way. This Court should "consider petitioner's claim in light of this Nation's historical antipathy to monopoly and of repeated congressional efforts to preserve and foster competition," and should "require a clear and certain signal from Congress before approving the position of a litigant who . . . argues that the beachhead of privilege is wider, and the area of public use narrower, than courts had previously thought." *Id.* at 530-31.

D. Congress Would Not Have Made Section 271 (e)(1) Depend Upon The Difficult And Indefinite Distinction Between Drugs And Devices

Medtronic's contention that Congress did not differentiate between "drugs" and "devices" in section 271(e)(1) is supported by the fact that a bright line between the two does not exist. In a similar situation, this Court noted that its "conclusion that neither the language of the Rule nor the intent of its framers call[ed] for a distinction between 'fact' and 'opinion' is strengthened by the analytical difficulty of drawing such a line." *Beech Aircraft Corp. v. Rainey*, 109 S. Ct. 439, 449 (1988).

Any attempted exclusion of devices from section 271 (e)(1) ignores the fact that "the industry, the courts and others—including [the FDA]—have found it difficult to draw a distinction between drugs and devices, and to know how narrowly or broadly to define devices."

Benson, *supra* note 31, at 99-100; Kahan, *supra* note 29, at 59 (drug/device distinction is one of the most "convoluted issues now facing the FDA").[35]

Definitional difficulty has arisen when a product combines features of both drugs and devices, and in drug delivery systems.[36] For instance, an atomizer or syringe is regulated as a device,[37] but if sold pre-filled with a drug, the entire system is regulated as a drug. Thus, according to Lilly, one could not do FDA testing during the patent term of an improved patented syringe, *unless* it was tested pre-filled with a drug. Congress cannot have meant the section 271(e)(1) testing exemption to depend on this meaningless difference.

35. The FDA Action Plan for 1990 states that resolving definitional problems between "drugs" and "devices" is an agency goal, and the FDA has formed a task force to address the problem. Kahan, *supra* note 29, at 62. *See also* Dept. of Health & Human Services, FDA, *A Plan For Action Phase III* (1989). Currently, both the Drug Center and the Device Center within the FDA have been required to create an office to resolve disputes over whether products are drugs or devices. Kahan, *FDA Regulation of Combination Drug and Device Products*, Clinica No. 327 at 13 (Nov. 23, 1988).

36. Products combining features of both drugs and devices include a bone cement with an antibiotic and a toothpaste with fluoride. The first was deemed a device, the second a drug. Similarly, the FDA found a condom with a spermicide is a device, but that a paper tissue impregnated with a germicidal agent is a drug. Dormer, *Drug/Device Distinctions . . . What Has Really Happened*, 41 Food Drug Cosm. L.J. 201, 205 (1986) [hereinafter Dormer]. Another difficulty is classifying products that "seem" more like drugs than devices. Barium sulfate, an injectable dye used as a contrast medium to enhance cancer-detecting x-rays, is regulated as a drug even though it does not operate by chemical or metabolic action. Difficulty exists with combination products where the device function is different than the drug (catheters tipped with antibiotic, pacemaker leads which elute steroids). In some cases, even use of human tissue is regulated as a device, although it plainly satisfies the definition of a biological product. Kahan, *supra* note 29, at 62. Implantable drug infusion pumps and skin patches which release drugs also create definitional problems. Kahan, Clinica No. 327 *supra* note 35, at 14.

37. Dormer, *supra* note 36, at 204 n.11.

For infringement to depend upon a drug/device distinction implicitly assumes that some authoritative entity will draw that line. But, it is unlikely that Congress would have given the FDA authority to make a classification decision that would determine the wholly unrelated question of patent infringement. The FDA's mission is to promote public health. It is guided by a statutory definition in classifying products as drugs or devices. (21 U.S.C. § 321 (g)(1) & (h) (1982)) but in gray areas the agency makes the classification by balancing safety and efficacy with the need to give the public speedy access to medicinal improvements.[38] Kahan, *supra* note 29, at 58. Definitions made in terms of those criteria do not form a rational basis for deciding infringement questions.[39] Furthermore, the FDA's decision-making process should not be skewed by adding unrelated patent consequences to the definitional equation.[40]

38. Furthermore, "the FDA has been known to be inconsistent in determining regulatory jurisdiction over products that arguably could be considered either drugs or devices." Kahan, *supra* note 29, at 59. The FDA also has reclassified products from drugs to devices. *Id.* at 62; 54 Fed. Reg. 27741.

39. The FDA's classification of condoms with spermicide is illustrative. Because the spermicide (a drug) was considered supplemental to the contraceptive purpose of the product, the FDA considered it a "device" and regulated it as such. However, when it was discovered that the spermicidal drug was also a viricide that killed the AIDS virus, the manufacturers wanted to advertise that effect. The FDA ruled that to do so would give the viricide effect prominence and would require reapproval of the entire product as a "drug." Kahan, *supra* note 29, at 61. Congress cannot have meant the availability of the infringement exemption to depend upon the purpose for which a product was advertised.

40. One commentator has publicly advised companies to take section 271(e)(1) considerations into account in deciding whether to lobby the FDA for a drug or device classification. *Id.*; Dormer, *supra* note 36, at 206.

Congress has long been aware of these definitional difficulties[41] and would not have made a patent infringement exemption depend on a distinction that often cannot be drawn.

IV. FDA-MANDATED TESTING OF DEVICES SHOULD NOT BE HELD TO BE PATENT INFRINGEMENT EVEN IF SECTION 271(e)(1) IS DEEMED INAPPLICABLE

The basis for the district court's holding that FDA-mandated experimental testing of a product can constitute patent infringement is the Federal Circuit's controversial decision in *Roche*. That decision relegated the long recognized concept of excusable experimental use to a "dilettante affair" since little if any modern experimentation is undertaken without any ultimate commercial purpose which *Roche* made the touchstone of infringing "use" under section 271(a). *Roche*, 733 F.2d at 863. *Roche* also had the effect of installing the "regulatory" patent as a firm reality for products subject to lengthy FDA testing. The swift reversal of the *Roche* decision by Congressional enactment of section 271(e)(1) was seen by the Federal Circuit as a "repeal by implication" of its conclusion that infringing "use" under section 271(a) included FDA testing. Pet. App. 6a (citing *United States v. Fausto*, 108 S. Ct. 668, 676 (1988)).

41. *See* Subcomm. on Oversight and Investigations, House Comm. on Energy and Commerce, 98th Cong., 1st Sess., Oversight Report on FDA Implementation of the Medical Device Amendments of 1976 (Comm. Print 98-F) (1983). *See also* Boguslaski, *Classification and Performance Standards under the 1976 Medical Device Amendments*, 40 Food Drug Cosm. L.J. 421, 422 (1985); Schwartz, *Performance Standards under the Medical Device Amendments: A Flawed Process in Need of Reform*, 39 Food Drug Cosm. L.J. 318 (1984); Dept. of Health & Human Services, FDA, *Working Relationships: Agreement Among the Bureaus of Medical Devices (BMD), Radiological Health (BRH), Biologics (BoB)* (1982); 44 Fed. Reg. 24236 (April 24, 1979).

If this Court were to decide that Congress overturned the *Roche* decision only with respect to drugs when it enacted section 271(e)(1), it still would be appropriate to inquire whether FDA-mandated testing of devices constitutes patent infringement in the first place.[42] The *de facto* extension of patent term created by the "regulatory patent" in the health field by FDA regulatory delay for devices such as the PCD, and the consequent anti-competitive and health inhibiting results, should not be countenanced. Absent a preclusive statute, this Court should hold, as a matter of precedent and patent policy, that pre-expiration testing of medical devices mandated by the FDA is not an infringement under the Patent Act.

Congress cannot grant patents for other than a limited time or in a way that does not promote progress in science.[43] Thus a patent grant cannot be perpetual or indefinite. Congress was well aware of that limitation when it stated the precise purpose of section 271(e)(1): "prevention of [FDA experimental] activity would extend the patent owner's commercial exclusivity beyond the patent expiration date." H.R. Rep. 98-857(1), *supra* p.7, at 45-46.

The regulatory barrier to free competition created by FDA testing delays after expiration of a patent contravenes the "congressional understanding" that "free exploitation of ideas will be the rule." *Bonito Boats*, 109 S. Ct. at 978; *Dubilier*, 289 U.S. at 186-187 (after

42. If *Roche* was a "narrow" holding as Lilly asserts (Pet. Br. 25), then the issue of whether FDA testing of medical devices is a "use" under section 271(a) has never been decided.

43. The Constitution empowers Congress "To promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." U.S. Const., art. I, § 8, cl. 8.

patent's expiration, public should have right to use invention "without restriction"); *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169, 185 (1896) ("[O]n the expiration of a patent the monopoly created by it ceases to exist.").

The mandate of *Scott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249 (1945), can be effectuated only if the Court reads the FD&C Act to have effectively created a testing exemption to the definition of "use" in 35 U.S.C. § 271(a).

> The nature and extent of the legal consequences of the expiration of a patent are federal questions, the answers to which are to be derived from the patent laws and the policies which they adopt. By the patent laws Congress has given to the inventor opportunity to secure the material rewards for his invention for a limited time. . . . and that upon the expiration of the patent the public be left free to use the invention.
>
> * * *
>
> The public has invested in [free use of the patent's disclosure] by the grant of a monopoly to the patentee for a limited time. *Hence any attempted reservation or continuation in the patentee or those claiming under him of the patent monopoly, after the patent expires, whatever the legal device employed, runs counter to the policy and purpose of the patent laws.*

Id. at 255-56. *See also Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 118 (1938); *Brulotte v. Thys Co.*, 379 U.S. 29, 31 (1964); *Boggild v. Kenner Products*, 776 F.2d 1315, 1318 (6th Cir. 1985), *cert. denied*, 477 U.S. 908 (1986) ("Hence, efforts to extend or

reserve the patent monopoly beyond the seventeen years contravene the policy and purpose of the patent laws.").

To the extent that the existence of FDA regulatory testing requirements confers market exclusivity on a patentee after the patent expires, it is in derogation of Congress' implementation of the Constitutional mandate in Article I, section 8, clause 8, and this Court's consistent practice of striking down any "attempted reservation or continuation" of the patent monopoly. *Scott Paper*, 326 U.S. at 256. Nothing in the FD&C Act was meant to perpetuate an effective monopoly as the Sixth Circuit recognized in *Upjohn Mfg. Co. v. Schweiker*, 681 F.2d 480 (6th Cir. 1982):

> The Federal Food, Drug, and Cosmetic Act and the underlying regulations governing the approval for the marketing of new drugs were not intended to provide patent-like protection for a seller who has gained approval of a pioneer new drug application.

Id. at 484. Perpetuating a "regulatory patent" violates the warning sounded by this Court in *Sears* that "the patent system is one in which uniform federal standards are carefully used to promote invention while at the same time preserving free competition." 376 U.S. at 230-31 (footnote omitted).

Contrary to the holding in *Roche*, the FDA testing performed by Medtronic in satisfaction of a Federal statutory requirement should be treated as a non-infringing experimental "use" analogous to the "fair use" permitted in the case of copyrights.

> Even copying for noncommercial purposes may impair the copyright holder's ability to obtain the rewards that Congress intended him to have. But a

> use that has no demonstrable effect upon the potential market for, or the value of, the copyrighted work need not be prohibited in order to protect the author's incentive to create. The prohibition of such noncommercial uses would merely inhibit access to ideas without any countervailing benefit.

Sony, 464 U.S. at 450-51.

Lilly is not the first patent holder that has attempted to use laws other than the patent statute to extend its monopoly position beyond patent expiration. In *Kellogg*, 305 U.S. 111, the patentee claimed that the design and appearance of the product (shredded wheat) had acquired "secondary meaning" and therefore was entitled to post-patent protection under the trademark laws. The Court held that the policy and purpose of the patent laws require that patented designs become public property after the seventeen year patent term, even if the designs have come to identify the product with a single source in the minds of the public. The Court unequivocally rejected the concept of *de facto* patent monopoly extension based on the trademark laws. *See also Lucien Lelong, Inc. v. Lander Co.*, 164 F.2d 395, 397-98 (2d Cir. 1947). More recently, in *Bonito Boats*, 109 S. Ct. at 971, this Court prevented the use of state law to create patent-like protection at odds with the policies of the Patent Act. This Court also should reject Lilly's attempt to use FDA regulation as a way of extending its patent in contravention of the Constitutional mandate and the unvarying policy of this Court to ensure that patents last only for a limited and definite time.

CONCLUSION

The judgment of the court of appeals should be affirmed.

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APPENDIX A

Selected Passages From The Legislative History of Section 201 (35 U.S.C. § 156) of Title II of the Drug Price Competition-Patent Term Restoration Act of 1984 (Emphasis added)

Remarks of Rep. Derrick, 130 Cong. Rec. H8703 (daily ed. Aug. 8, 1984):

> It is hoped that this extension of exclusive rights will encourage increased research and development efforts by *pharmaceutical companies.*
>
> * * *
>
> It also helps to restore the incentive of patent protection to those *drug manufacturers* that spend millions upon millions of dollars in the search for new drugs.

Remarks of Rep. Waxman, 130 Cong. Rec. H8706 (daily ed. Aug. 8, 1984):

> Research-intensive firms predict that declining patent term will result in the development of fewer innovative products.

Remarks of Rep. Kastenmeier, 130 Cong. Rec. H8708 (daily ed. Aug. 8, 1984):

> In response to the problems of the *research-based pharmaceutical houses,* legislation was offered to restore patent life lost through regulatory review.
>
> * * *
>
> The OTA (Office of Technology Assessment) study, "Patent Term Extension and the Pharmaceutical In-

dustry," found that since 1966 the average effective *patent terms of drugs* had declined.

* * *

[T]he FDA has erected a set of substantial barriers to the market entry of *generic substitutes.*

* * *

The failure of patent term legislation last Congress was primarily the result of our failure to view the regulatory and patent problems of the *drug industry* as a whole, as recommended by OTA.

Remarks of Rep. Hyde, 130 Cong. Rec. H8709-10 (daily ed. Aug. 8, 1984):

However, for certain products such as *chemicals and medications,* the 17-year patent term has been unintentionally eroded by Federal premarket testing and regulations.

* * *

Shorter patent life translates into falling rates of return, which translates into falling investment in research and development, which translates into fewer and fewer new *medicines* coming on the market.

* * *

This reduction in the number of *drug innovations* strongly indicates that the public is being deprived of new therapies. The decline in *pharmaceutical patent* lives, the result of inadvertence rather than congressional intent, will erode the investment research incentive provided by the traditional 17-year patent term.

Remarks of Rep. Rodino, 130 Cong. Rec. H8713 (daily ed. Aug. 8, 1984):

The *pharmaceutical industry* in the United States has long been an important element of our economic physical well-being.

* * *

The *pharmaceutical industry* will benefit substantially under this bill.

* * *

Although Congress never intended it, the time consumed in meeting these FDA requirements is, in effect, subtracted from the *patent lives of drugs.*

* * *

Under the bill H.R. 3605, for every *drug* they test and have reviewed at the Food and Drug Administration [FDA], a generally corresponding patent term extension will be available. The availability of such a patent term extension has long been an important legislative goal for *the industry.* It is my hope that with enactment of this bill we will see a blossoming of new research and development activities. Once patent term restoration becomes law there will be an added incentive to pursue research for new drug products.

Remarks of Rep. Minish, 130 Cong. Rec. H9143 (daily ed. Aug. 8, 1984):

Extension was included to help protect the investment in research and development that manufacturers undertake to develop *pioneer drugs.*

APPENDIX B

Selected Passages From The Legislatuve History of Section 201 (35 U.S.C. §§ 156 & 271(e)) of the Generic Animal Drug and Patent Term Restoration Act (Emphasis added)

Report of Senate Committee on Labor and Human Resources on S.2407, S. Rep. No. 448, 99th Cong. 2d Sess. at 2, 13 (1986):

> This bill is modeled after the Drug Price Competition and Patent Term Restoration Act of 1984 ("DPC/PTR"), Pub. Law 98-417. Its purpose is to extend to veterinary drugs and biologicals the generic competition and restored patent life *afforded human pharmaceuticals by the DPC/PTR Act.*
>
> * * *
>
> The bill adopts entirely the patent term restoration formula and process that Congress concluded was *appropriate for human pharmaceuticals and biologics in 1984.*
>
> * * *
>
> Section 202 [35 U.S.C. § 156]: This section adds veterinary drugs and biologics into the patent term restoration formula that *already exists for human drugs and for food additives,* including those intended for use in animal feed.
>
> * * *
>
> Section 203 [35 U.S.C. § 271(e)]: This section amends Section 271 of Title 35 to provide that it is not an act of patent infringement to make or use an animal drug or veterinary biological for purposes reasonably related to developing information for a submission to FDA. A similar provision applies to *human pharmaceuticals.*

House Report on H.R. 4892, H.R. Rep. No. 972, 100th Cong., 2d Sess., pt. 1, at 2, 3, pt. 2 at 15 (1988):

> The purpose of the bill is to create in the animal drug industry similar conditions for generic drugs and patent term restoration *as Congress did in the human drug industry in 1984* with the "Drug Price Competition and Patent Term Restoration Act" (Public Law 98-417).
>
> * * *
>
> H.R. 4982 thus would extend to animal drug products *those benefits already established for human drugs* through the "Drug Price Competition and Patent Term Restoration Act" of 1984.

Remarks of Rep. Kastenmeier on H.R. 4892, 134 Cong. Rec. H9786 (daily ed. Oct. 6, 1988):

> In 1984 — after 5 years of legislative effort — the Congress enacted a set of rules to govern the granting of patent term extension *for human drugs.*

Opening statement of Sen. Hatch, *Animal Drug Amendments and Patent Term Restoration Act of 1986: Hearing on S. 2407 Before the Senate Comm. on Labor and Human Resources,* 99th Cong., 2d Sess. 1 (1986):

> [T]he Drug Price Competition and Patent Term Restoration Act . . . had two simple goals. First, to encourage competition *in the pharmaceutical industry* by dramatically expanding the Food and Drug Administration's ability to approve generic drugs. And second, to provide an incentive *for the research-based pharmaceutical companies* to continue their trail-blazing efforts at research and development by restoring marketing time lost during the expensive and time-consuming FDA approval process.